straw, concentrate of poppy straw, morphine for further manufacture and other crude alkaloids.

- (c) The detail sheets (DEA 247(c)) supporting the summary of manufacture from poppy straw or concentrate of poppy straw shall show separately the amount of poppy straw or concentrate imported, the poppy straw used for production of concentrate, the concentrate used for extraction of alkaloids, subsequent manufacture from those alkaloids and the inventory of poppy straw and concentrate of poppy straw at the close of the reporting period.
- (d) Upon importation of poppy straw or concentrate of poppy straw, samples will be selected and assays made by the importing manufacturer in a manner and according to a method previously approved by DEA. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.
- (e) Upon withdrawal of poppy straw or concentrate of poppy straw from Customs custody, the importing manufacturer shall assign to each lot or container an identification number by which the poppy straw or concentrate will be associated with the lot assay and identified in reports.
- (f) Where factory procedure is such that partial withdrawals of poppy straw or concentrate are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.
- (g) Concentrate of poppy straw and derivatives produced for exclusive use in further manufacturing purposes shall be reported produced when they come into existence in that form in which they are to be so used. Alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Products manufactured

partly for distribution and partly for use in further manufacture will be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

- (h) Subject to §1303.24(c) of this chapter, no accumulations of morphine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process for an unreasonable time in light of efficient industrial practices. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks, and reported as produced.
- (i) In making conversions of concentrate of poppy straw alkaloids and their salts to anhydrous morphine the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multiplied by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the respective molecular weight of such alkaloid or salt and the molecular weight of anhydrous morphine (285.16), such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopoeia.

[40 FR 6779, Feb. 14, 1975, as amended at 40 FR 42866, Sept. 17, 1975; 46 FR 28841, May 29, 1981. Redesignated at 49 FR 37060, Sept. 21, 1984. Redesignated and amended at 51 FR 5319, 5320, Feb. 13, 1986]

### PART 1305—ORDER FORMS

Sec. Scope of Part 1305. Distributions requiring order forms. 1305.04 Persons entitled to obtain and execute order forms. 1305.05 Procedure for obtaining order forms. Procedure for executing order forms. 1305.06 1305.07 Power of attorney. Persons entitled to fill order forms. 1305.08 1305.09 Procedure for filling order forms. 1305 10 Procedure for endorsing order forms. 1305.11 Unaccepted and defective order forms. 1305.12 Lost and stolen order forms.

1305.13 Preservation of order forms.

1305.14 Return of unused order forms.

1305.15 Cancellation and voiding of order forms.

1305.16 Special procedure for filling certain order forms.

AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

SOURCE: 36 FR 7796, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

### §1305.01 Scope of Part 1305.

Procedures governing the issuance, use, and preservation of order forms pursuant to section 1308 of the Act (21 U.S.C. 828) are set forth generally by that section and specifically by the sections of this part.

### §1305.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

- (a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).
- (b) The term *purchaser* means any registered person entitled to obtain and execute order forms pursuant to §1305.04 and §1305.06.
- (c) The term *supplier* means any registered person entitled to fill order forms pursuant to §1305.08.
- (d) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) and §§ 1301.02 and 1302.02 of this chapter.

### § 1305.03 Distributions requiring order forms.

An order form (DEA Form 222) is required for each distribution of a controlled substance listed in Schedule I or II, except for the following:

- (a) The exportation of such substances from the United States in conformity with the Act;
- (b) The delivery of such substances to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business (but excluding such carriage or storage by the owner of the substance in connection with the distribution to a third person);

- (c) The procurement of a sample of such substances by an exempt law enforcement official pursuant to §1301.26(b) of this chapter, provided that the receipt required by that section is used and is preserved in the manner prescribed in this part for order forms;
- (d) The procurement of such substances by a civil defense or disaster relief organization, pursuant to §1301.27 of this chapter, provided that the Civil Defense Emergency Order Form required by that section is used and is preserved with other records of the registrant; and
- (e) The purchase of such sustances by the master or first officer of a vessel pursuant to §1301.28 of this chapter: *Provided,* That copies of the record of sale are generated, distributed and preserved by the vendor according to that section.
- (f) The delivery of such substances to a registered analytical laboratory, or its agent approved by DEA, from an anonymous source for the analysis of the drug sample, provided the laboratory has obtained a written waiver of the order form requirement from the Special Agent in Charge of the Area in which the laboratory is located, which waiver may be granted upon agreement of the laboratory to conduct its activities in accordance with Administration guidelines.

[36 FR 7796, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 15031, Apr. 30, 1974; 47 FR 41735, Sept. 22, 1982; 50 FR 31590, Aug. 5, 1985; 51 FR 5320, Feb. 13, 1986; 53 FR 4963, Feb. 19, 1988]

# §1305.04 Persons entitled to obtain and execute order forms.

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in Schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in Schedule I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

### § 1305.05

(b) An order form may be executed only on behalf of the registrant named thereon and only if his registration as to the substances being purchased has not expired or been revoked or suspended.

# § 1305.05 Procedure for obtaining order forms.

- (a) Order Forms are issued in mailing envelopes containing either seven or fourteen forms, each form containing an original duplicate and triplicate copy (respectively, Copy 1, Copy 2, and Copy 3). A limit, which is based on the business activity of the registrant, will be imposed on the number of order forms which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.
- (b) Any person applying for a registration which would entitle him to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him to obtain order forms may requisition such forms for the first time by contacting any Division Office or the Registration Unit of the Administration. Any person already holding order forms may requisition additional forms on DEA Form 222a which is mailed to a registrant approximately 30 days after each shipment of order forms to that registrant or by contacting any Division Office or the Registration Unit of the Administration. All requisition forms (DEA Form 222a) shall be submitted to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.
- (c) Each requisition shall show the name, address, and registration number of the registrant and the number of books of order forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to §1305.07.

(d) Order forms will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Unit of the Administration by returning the forms with notification of the error.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 53 FR 4963, Feb. 19, 1988]

## §1305.06 Procedure for executing order forms.

- (a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.
- (b) Only one item shall be entered on each numbered line. There are ten lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for carfentanil etorphine hydrochloride and diprenorphine shall contain only these substances. The total number of items ordered shall be noted on that form in the space provided.
- (c) An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item the form shall show the name of the article ordered, the finished or bulk form of the article (e.g., 10-milligram tablet, 10-milligram concentration per fluid ounce or milliliter, or U.S.P.), the number of units or volume in each commercial or bulk container (e.g., 100-tablet bottle or 3milliliter vial) or the quantity or volume of each bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the article if not in pure

form. The catalogue number of the article may be included at the discretion of the purchaser.

(d) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any one form.

(e) Each order form shall be signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to §1305.05(c). The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 17838, May 21, 1974; 53 FR 4963, Feb. 19, 1988; 54 FR 33674, Aug. 16, 1989]

### §1305.07 Power of attorney.

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed (or was authorized to sign, pursuant to §1301.32(f) of this chapter or §1311.32(f) of this chapter) the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked. The form for the power of attorney and notice of revocation shall be similar to the following:

Power of Attorney for DEA Order Forms
(Name of registrant) (Address of registrant) (DEA registration number)
I, ———— (name of person
granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant
under the Controlled Substances Act or Con-
trolled Substances Import and Export Act,
have made, constituted, and appointed, and
by these presents, do make, constitute, and
appoint (name of at-
torney-in-fact), my true and lawful attorney
for me in my name, place, and stead, to exe-
cute applications for books of official order
forms and to sign such order forms in req-
uisition for Schedule I and II controlled sub-
stances, in accordance with section 308 of the
Controlled Substances Act (21 U.S.C. 828) and
part 305 of Title 21 of the Code of Federal
Regulations. I hereby ratify and confirm all
that said attorney shall lawfully do or cause
to be done by virtue hereof.

(Signature of person granting power)

(Signature of attorney-in-fact)
Witnesses:
1
2. ————.
Signed and dated on the day of
, 19, at

### NOTICE OF REVOCATION

(Signature of person r	revoking	power)
Witnesses:		

WICHCOSCS.	
1. —————	_
2	_

### § 1305.08

[37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

# §1305.08 Persons entitled to fill order forms.

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedule I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

- (a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing business or if his registration is expiring without reregistration, may dispose of any controlled substances listed in Schedule I or II in his possession pursuant to order forms in accordance with §1307.14 of this chapter;
- (b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person;
- (c) A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, §1307.11 of this chapter; and
- (d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a controlled substance listed in Schedule I or II to another person registered or authorized to conduct chemical analysis, instructional activities, or research with such substances pursuant to the order form of the latter person, if such distribution is for the purpose of furthering such chemical analysis, instructional activities, or research.
- (e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcot-

ics, is authorized to fill order forms for distribution of narcotic drugs to offsite narcotic treatment programs only.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971; 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FR citations affecting §1305.08, see the List of CFR Sections Affected in the Finding Aids section of this volume

# §1305.09 Procedure for filling order forms.

- (a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier, and retain Copy 3 in his own files.
- (b) The supplier shall fill the order, if possible and if he desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section
- (c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Administration on the order form, except as specified in paragraph (f) of this section.
- (d) The supplier shall retain Copy 1 of the order form for his ovn files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.
- (e) The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

# §1305.10 Procedure for endorsing order forms.

(a) An order form made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in §1305.09 may be endorsed to another supplier for filling. The endorsement hall be made only by the supplier to whom the order form was first made, shall state (in the spaces provided on the reverse sides of Copies 1 and 2 of the order form) the name and address of the second supplier, and shall be signed by a person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier shall fill the order, if possible and if he desires to do so, in accordance with §1305.09 (b), (c), and (d), including shipping all substances directly to the purchaser.

(b) Distributions made on endorsed order forms shall be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

# §1305.11 Unaccepted and defective order forms.

- (a) No order form shall be filled if it: (1) Is not complete, legible, or prop-
- erly prepared, executed, or endorsed; or (2) Shows any alteration, erasure, or change of any description.
- (b) If an order form cannot be filled for any reason under this section, the

supplier shall return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, Copies 1 and 2 of the order form and the statement shall be attached to Copy 3 and retained in the files of the purchaser in accordance with §1305.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

#### § 1305.12 Lost and stolen order forms.

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with Copy 3 of the order form first executed. A copy of the statement shall be attached to Copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof "Not accepted" and return Copies 1 and 2 to the purchaser, who shall attach it to Copy 3 and the statement.

(b) Whenever any used or unused order forms are stolen from or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers. If an entire book of order

### § 1305.13

forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Registration Branch of the Administration shall immediately be notified.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986]

#### §1305.13 Preservation of order forms.

- (a) The purchaser shall retain Copy 3 of each order form which has been filled. He shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.
- (b) The supplier shall retain Copy 1 of each order form which he has filled.
- (c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of 2 years. If a purchaser has several registered locations, he must retain Copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to §1305.06(e)) at the registered location printed on the order form.
- (d) The supplier of carfentanil etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other order forms and records required to be maintained by the registrant.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 17839, May 21, 1974; 54 FR 33674, Aug. 16, 1989]

# §1305.14 Return of unused order forms.

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to §§ 1301.45 or 1301.46

of this chapter as to all controlled substances listed in Schedules I and II for which he is registered, he shall return all unused order forms for such substance to the nearest office of the Administration.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

# §1305.15 Cancellation and voiding of order forms.

- (a) A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.
- (b) A supplier may void part or all of an order on an order form by notifying the purchaser in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in paragraph (a) of this section.
- (c) No cancellation or voiding permitted by this section shall affect in any way contract rights of either the purchaser or the supplier.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

# §1305.16 Special procedure for filling certain order forms.

- (a) The purchaser of carfentanil etorphine hydrochloride or diprenorphine shall submit copy 1 and 2 of the order form to the supplier and retain copy 3 in his own files.
- (b) The supplier, if he determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the Administrator to handle these substances shall fill the order in accordance with the procedures set forth in § 1305.09 except that:
- (1) Order forms for carfentanil etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities and (2) the substances shall only be shipped to the purchaser at the location printed by the Administration

upon the order form under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.

[39 FR 17839, May 21, 1974, as amended at 54 FR 33674, Aug. 16, 1989]

### PART 1306—PRESCRIPTIONS

Sec.

#### GENERAL INFORMATION

- 1306.01 Scope of Part 1306.
- 1306.02 Definitions.

cotic drugs

- 1306.03 Persons entitled to issue prescriptions.
- 1306.04 Purpose of issue of prescription.
- 1306.05 Manner of issuance of prescriptions.
- 1306.06 Persons entitled to fill prescriptions. 1306.07 Administering or dispensing of nar-

# CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

- 1306.11 Requirement of prescription.
- 1306.12 Refilling prescriptions.
- 1306.13 Partial filling of prescriptions.
- 1306.14 Labeling of substances.
- 1306.15 Filing of prescriptions.

### CONTROLLED SUBSTANCES LISTED IN SCHEDULES III AND IV

- 1306.21 Requirement of prescription.
- 1306.22 Refilling of prescriptions.
- 1306.23 Partial filling of prescriptions.
- 1306.24 Labeling of substances.
- 1306.25 Filing prescriptions.
- 1306.26 Transfer between pharmacies of presription information for Schedules III, IV, and V controlled substances for refill purposes.

## Controlled Substances Listed in Schedule V

- 1306.31 Requirement of prescription.
- 1306.32 Dispensing without prescription.

AUTHORITY: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

### GENERAL INFORMATION

### §1306.01 Scope of Part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

### §1306.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

- (a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801).
- (b) The term *individual practitioner* means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.
- (c) The term *institutional practitioner* means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.
- (d) The term *pharmacist* means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., a pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.
- (e) A Long Term Care Facility (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.
- (f) The term *prescription* means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate used. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)
- (g) The terms *register* and *registered* refer to registration required and permitted by section 303 of the Act (21 U.S.C. 823).
- (h) The term *home infusion pharmacy* means a pharmacy which compounds solutions for direct administration to a patient in a private residence, Long Term Care Facility or hospice setting by means of parenteral, intravenous,